



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/576,778	05/23/2000	Martin Schulein	5843.200-US	1722

25908 7590 03/12/2002

NOVOZYMES NORTH AMERICA, INC.
C/O NOVO NORDISK OF NORTH AMERICA, INC.
405 LEXINGTON AVENUE, SUITE 6400
NEW YORK, NY 10174

EXAMINER

RAO, MANJUNATH N

ART UNIT	PAPER NUMBER
----------	--------------

1652

DATE MAILED: 03/12/2002 //

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/576,778

Applicant(s)

SCHULEIN ET AL.

Examiner

Manjunath N Rao

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 6-21, 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-5 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-26 are still pending and are present for examination.

Election/Restrictions

Applicant's election with traverse of Group I, Claims 1-5, 22-24 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that coexamination of Groups I and III would not be a serious burden. This is not found persuasive because while the searches for the two groups overlap, they are not coextensive. The search for Groups I and III would each require the search of subclasses unnecessary for the search of elected Group II. For example, search of Group I would require search of subclass 435/209 and search of Group III would require search of subclass 435/277.

The requirement is still deemed proper and is therefore made FINAL.

Claims 6-21, 25-26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 10. However, when claims 1-5, 22-24 directed to a product, become allowable, pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claim 26, directed to the process of using the patentable product, will be rejoined by the Examiner.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been received in this Application. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is also acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 and claims 2-5, 22-23 which depends from claim 1 are rejected under 35

U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is rejected because of the confusion in the SEQ ID Nos claimed. Claim 1 is directed to an enzyme selected from a group consisting of a polypeptide encoded by the "DNA sequence of positions 76-1455 of SEQ ID NO:1", an enzyme "having a sequence of at least 75% identity to positions 26-485 of SEQ ID NO:2". However, a perusal of sequences filed in the application indicates that SEQ ID NO:1 is a short DNA comprising only 42 nucleotides and SEQ ID NO:2 is not an amino acid sequence, but also a DNA sequence comprising only 64 nucleotides. Amending the claim to include the right SEQ ID Nos will overcome this rejection. For purposes of examination it is presumed that applicants intended to recite SEQ ID NO:9 and 10 as these are the nucleotide and amino acid sequences of the beta-1,4-endoglucanase of the instant application.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 is directed to an enzyme with endoglucanase activity selected from a group consisting of a polypeptide comprising an amino acid sequence from amino acid 26-646 of SEQ ID NO:2 (i.e., SEQ ID NO:10) and "an analogue of the polypeptide which is at least 75% homologous with the polypeptide". It is highly unclear to the Examiner as to which is the

Art Unit: 1652

polypeptide that is being compared with. In other words, it is not clear to the Examiner as to which polypeptide should the analogue be homologous to. If the applicants are comparing it with SEQ ID NO:2 (i.e., SEQ ID NO:10), then amending the claim appropriately would overcome this rejection.

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 24 is rejected because it is rendered indefinite as it depends from a non-elected claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 22, 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Dhillon et al. (Biotechnol. Lett, Vol. 7(9):695-697, 1985). This rejection is based upon the public availability of a printed publication. Claims 1-5 and 22, 24 of the instant application are drawn to an endoglucanase selected from a group consisting of a polypeptide encoded by a DNA sequence, positions 76-1455 of SEQ ID NO:1 (i.e., SEQ ID NO:9) or a polypeptide produced by culturing a cell comprising the above DNA sequence under conditions wherein the DNA sequence is expressed, a polypeptide having a sequence of at least 75% identity to positions 26-485 of SEQ

Art Unit: 1652

ID NO:2 (actually SEQ ID NO:10) and a polypeptide encoded by DNA sequence from the plasmid in *E.coli* DSM 12805 (claim 1), the endoglucanase belonging to the family 9 of glycosyl hydrolases (claim 2), the enzyme which is endogenous to *B.licheniformis*, ATCC 14580 (claim 3), the enzyme which exhibits the enzymatic activity in the pH range of 4-11 (claim 4), the enzyme selected from a group consisting of the polypeptide comprising an amino acid sequence as shown in positions 26-646 of SEQ ID NO:2 and an analogue of the same (claim 5), a composition comprising the above enzyme (claim 22) and the enzyme which is free from homologous impurities and prepared by culturing the bacteria harboring the DNA encoding the enzyme (claim 24). A perusal of the specification indicates that the above enzyme was isolated from a publicly available *B.licheniformis* ATCC 14580. Dhillon et al. disclose an endoglucanase obtainable from a strain of *B.licheniformis*-1 which is active in the pH range 4-11. The reference also discloses a composition comprising the enzyme and a method of obtaining the enzyme by growing the culture comprising a DNA which encodes the above enzyme. Based on the characteristics provided in the reference (i.e., the source of the enzyme and the activity in the pH range 4-11) and in the above claims, Examiner takes the position that the enzyme in the reference and the instant enzyme and the respective *B.licheniformis* strain from which the enzymes are obtained are one and the same even though the reference does not recite the same strain and other characteristics such as the enzyme belonging to family 9 or the amino acid sequence information. Even though the reference does not disclose any amino acid sequence information or classify the enzyme as belonging to "family 9", such characteristics are inherent to the enzyme. Therefore, the enzyme in the reference has either the same sequence as that in the

Art Unit: 1652

instant application or is at least 75% identical to the amino acid sequence with SEQ ID NO:2.

Therefore, Dhillon et al. anticipate claims 1-5, 22, 24 of this application as written.

Since the Office does not have the facilities for examining and comparing applicants' bacterial strain and the enzyme with the bacterial strain and the enzyme of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dhillon et al. as applied to claims 1-5, 22 and 24 above, and further in view of Olsen et al. (WO 95/26398, 10-5-1995). Claim 23 in this instant application is drawn to a composition comprising the endoglucanase (of claim 1) further comprising an enzyme selected from a group consisting of proteases, cellulases, hemicellulases etc.

As described in the previous paragraphs, Dhillon et al. teach an endoglucanase obtainable from a strain of *B.licheniformis*-1 which is active in the pH range 4-11. However, the

Art Unit: 1652

reference does not teach a composition of the enzyme further comprising other enzymes such as protease or hemicellulases.

Olsen et al. teach an enzyme preparation comprising a cellulase (an endoglucanase). Even though the enzyme is not from *B.licheniformis*, the reference does teach the importance of endoglucanase in the detergent making industry. The reference explicitly teaches that the Beta-1,4-bond hydrolyzing capacity of the enzyme is made use of in paper-making and baking industry as well. The reference also teaches the use of the endoglucanase enzyme in compositions comprising additional enzymes such as proteases and hemicellulases (see claim 13).

It would have been obvious to one skilled in the art at the time the invention was made to use the enzyme provided by Dhillon et al. and prepare a composition comprising additional enzyme such as a protease or hemicellulase as taught by Olsen et al. for use either as a detergent additive or in baking and paper-making industry. This is because while Dhillon et al. points towards the source of the enzyme, Olsen et al. describe in detail the use of such endoglucanases in the industry. One of ordinary skill in the art would have been motivated to do so as Dhillon et al. teach an endoglucanase that can be easily made from a bacillus culture and Olsen et al. provide a number of uses for such enzyme either alone or along with other enzymes. One skilled in the art would have a reasonable expectation of success since Dhillon et al. provides the enzyme and Olsen et al. demonstrates the use of the enzyme along with other enzymes.

Therefore the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art.

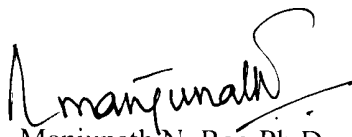
Art Unit: 1652

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is (703) 306-5681. The Examiner can normally be reached on M-F from 7:30 a.m. to 4:00 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Manjunath N. Rao Ph.D.
3/11/02